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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,096	10/12/2001	Anthony David Baxter	CIBT-P02-105	1908

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,096

Applicant(s)

BAXTER ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-93 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims I-16, drawn to a pharmaceutical composition comprising an aqueous solution of a pharmaceutically acceptable salt of a compound represented in the claimed formula(I), classified in class 514, subclass 217.03, 330, or more+ .
 - II. Claims 17-31, drawn to a pharmaceutical composition comprising an aqueous solution of a pharmaceutically acceptable salt of a compound represented in the claimed formula(II), classified in class 514, subclass 352, 354,+ .
 - III. Claim 32, drawn to a method for inhibiting activation of a hedgehog pathway in a cell comprising contacting the cell with the formulation(I) .
 - IV. Claim 32, drawn to a method for inhibiting activation of a hedgehog pathway in a cell comprising contacting the cell with the formulation (II).
 - V. Claim 33, drawn to a method for treating or preventing basal cell carcinoma, comprising administering an effective amount of the formulation (I).
 - VI. Claim 34, drawn to a method for treating or preventing basal cell carcinoma, comprising administering an effective amount of the formulation (II).

- VII. Claims 36-46, drawn to a pharmaceutical composition comprising an aqueous solution of a pharmaceutically acceptable salt of a compound represented in the claimed formula(III), classified in class 514, subclass 426, +.
- VIII. Claims 47-58, drawn to a pharmaceutical composition comprising an aqueous solution of a pharmaceutically acceptable salt of a compound represented in the claimed formula(IV), classified in class 514, subclass 422+.
- VIII. Claim 59, drawn to a method for inhibiting activation of a hedgehog pathway in a cell comprising contacting the cell with the formulation (III).
- X. Claim 60, drawn to a method for inhibiting activation of a hedgehog pathway in a cell comprising contacting the cell with the formulation (IV).
- XI. Claim 61, drawn to a method for treating or preventing basal cell carcinoma, comprising administering an effective amount of the formulation (III).
- XII. Claim 62, drawn to a method for treating or preventing basal cell carcinoma, comprising administering an effective amount of the formulation (IV).
- XIII. Claims 63-76, drawn to a pharmaceutical composition comprising an aqueous solution of a pharmaceutically acceptable salt of a compound represented in the claimed formula(V), classified in class 514, subclass 336, +.

- XIV. Claim 77, drawn to a method for inhibiting activation of a hedgehog pathway in a cell comprising contacting the cell with the formulation (V).
- XV. Claim 78, drawn to a method for treating or preventing basal cell carcinoma, comprising administering an effective amount of the formulation (V).
- XVI. Claims 79-91, drawn to a pharmaceutical composition comprising an aqueous solution of a pharmaceutically acceptable salt of a compound represented in the claimed formula(VI), classified in class 514, subclass 423,+ .
- XVII. Claim 92, drawn to a method for inhibiting activation of a hedgehog pathway in a cell comprising contacting the cell with the formulation (VI).
- XVIII. Claim 93, drawn to a method for treating or preventing basal cell carcinoma, comprising administering an effective amount of the formulation (V).

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions (I, II, VII, VIII, XIII, XVI) and (III-VI, VIII-XII, XIV-XV, XVII-XVIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

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3. Inventions (III,IV,VIII,X,XIV,XVII) and (V,VI,XI,XII,XV,XVIII) are not related because the biological pathway(i.e. hedgehog pathway) is not only pathway that is responsible for the basal cell carcinoma. Since the disease can be mediated by different pathway, each invention is patentably distinct to each other.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for each group is not same, wherein a reference which anticipates the invention of Group I would not render the invention of Group II -XVIII obvious, absent ancillary art, restriction for examination purposes as indicated is proper. Even if there were unity of classification, the search of entire groups and/or genus in the non-patent literature(especially, non-patent literature) and database search (a significant part of a thorough examination) would be burdensome, it is undue burden for examiner for the accurate and proper examination, restriction for examination purposes as indicated is proper.

Election of Species requirement

4. Upon the election of the patentably distinct invention mentioned immediately above, applicant is further required to elect the species as follows; This application contains claims directed to the patentably distinct species of the claimed invention.

Patentably distinct markush species are independent inventions, *In re Webber*, 198 USPQ 328, *In re Haas*, 198 USPQ 334. Divisional applications may be filled under 35 USC 121, as a result of an office requirement for an election of a patentably distinct species as made herein. *In re Joyce*, 115 USPQ 412. This satisfies the " patentably

distinct" criterion since the examiner is not of the opinion that various species are obviously unpatentable over one another and each species (as noted above) is capable of independent manufacture, use, and sale, with the other components of the claimed formulations.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

The generic claims are 1, 17, 36, 47, 63, 79 wherein each patentably distinct formula was described.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Patent examiner
October 7, 2002
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